

SHIPPED: 2-1-58 and 7-11-58, from Chicago, Ill., by Solo Laboratories.

LABEL IN PART: (Jar) "Eileen Cortney Multi-Formula X21 * * * Beauty through the Ages. A balanced topical tissue nutritive compound in a rich base with medicinal quantities of Lecithin, Poly-unsaturates (Vitamin F) and G-11, a prophylactic. Eileen Cortney Inc.—New York Distr. Net Weight 8 oz." "Eileen Cortney Multi-Formula X21 Pentracin Net Weight 4 oz. * * * A topical tissue nutritive with medical values of STABILIZED Polyunsaturates (5%)."

ACCOMPANYING LABELING: Leaflets entitled "For a Healthier Skin" and "Eileen Cortney's Manual of Instructions."

RESULTS OF INVESTIGATION: The leaflets were prepared by Dewey Windale, president of Solo Laboratories, and printed at Sayville, N.Y. The term "G-11" appearing on the label of the 8-oz. jars is the registered trade name of hexachlorophene.

LIBELED: 7-24-58, E. Dist. N.Y.

CHARGE: 502(a)—the labeling of the article, when shipped and while held for sale, contained false and misleading representations that the article was a skin nutritive and an adequate and effective treatment for pre-aged, degenerated skin, psoriasis, all types of flabby, scaly, itching skin, wrinkles, infantile eczema, and atopic dermatitis; 502(e) (2)—the label of the article failed to bear the common or usual name of each active ingredient; and 502(f) (1)—the labeling of the article failed to bear adequate directions for use in that the article was offered as a prophylactic, yet it failed to name the conditions for which its use would produce prophylaxis.

DISPOSITION. 8-26-58. Default—destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

DRUGS AND DEVICES FOR HUMAN USE*

5751. D.A.G. antiseptic. (F.D.C. No. 41182. S. Nos. 24-018/9 M.)

INFORMATION FILED: 5-16-58, S. Dist. Calif., against Melchior T. Dikkers, Los Angeles, Calif.

SHIPPED: 1-27-56 and 6-25-56, from California to Arizona.

LABEL IN PART: (Btl.) "Net Contents 4 Ounces or ["One Pint"] D.A.G. Antiseptic * * * Manufactured by Dikkers Biochemical Laboratory, Los Angeles, California.

CHARGE: 501(c)—the strength of the article, when shipped, differed from, and its purity and quality fell below, that which it purported and was represented to possess, in that the article was represented as an antiseptic, whereas it was not an antiseptic but was contaminated with viable organisms. 502(a)—the statements in the labeling of the article, namely, "Antiseptic * * * for minor irritations, cuts, bruises, burns." were false and misleading since the article was not antiseptic, was contaminated with viable organisms, and was not adequate and effective in the treatment of minor irritations, cuts, bruises, and burns. The accompanying labeling of the article, namely, leaflets entitled "D.A.G. Dikkers Antiseptic and Germicide." and "D.A.G. a Theratropic Seaweed Extract with Tri-Iodophenols An Ethical Product for the Dental Profession." contained false and misleading representations

*See also Nos. 5744, 5749.

that the article was adequate and effective in the treatment of periodontal disease, Vincent's infection, pyorrhea, oral surgery, trench mouth, throat irritations, burns, skin irritations, boils, cuts, abrasions, scratches, prophylaxis for men, rectal irritations, hemorrhoids, colon therapy, athlete's foot, eye irritations, infections, scalds, dermatitis, x-ray lesions, conjunctivitis, iritis, corneal ulcers, chemical burns, coryza, otitis media, sinusitis, tonsillitis, laryngitis, thrush, pruritis anus, fissures, fistula, colitis, amoeba infections, malignancy, gonorrhea, venereal prophylaxis, prostate inflammation, cystitis, hydrocele, leucorrhea, Trichomonas, endometritis, cervicitis, influenza, intestinal and focal toxemia, arthritis, gastric ulcer, duodenal ulcer, thyroid deficiency, cystic goiter, erysipelas, gangrene, carbuncles, furunculosis, abscesses, ulcerations, abrasions, bedsores, and incisions.

PLEA: Guilty.

DISPOSITION: 10-27-58. The defendant was fined \$300 and sentenced to jail for 1 year. The court suspended 11 months of the jail sentence and placed the defendant on probation for 5 years on condition that he serve 30 days in jail.

5752. Digitalis powder, digitalis tablets, and digitalis capsules. (F.D.C. No. 42207. S. Nos. 8-567/9 P.)

QUANTITY: 3 10-lb. tins of *digitalis powder*, 64,000 *digitalis tablets* in bottles, and 17,300 *digitalis capsules* in bottles, at Pittsburgh, Pa.

SHIPPED: The *digitalis powder* was shipped on 11-18-58, from New York, N.Y., after having been imported from England.

RESULTS OF INVESTIGATION: The *digitalis tablets* and *digitalis capsules* were manufactured at Pittsburgh, Pa., from *digitalis powder* which had been shipped in bulk as described above.

LIBELED: 9-24-58, W. Dist. Pa.

CHARGE: 501(b)—the strength of the digitalis powder, tablets, and capsules, while held for sale, differed from the standards for such drugs set forth in the United States Pharmacopeia; 502(a)—the following label statements: (powdered digitalis) "10 International Units of activity in 1.0 gramme" (The U.S.P. Digitalis Unit was set by the U.S.P. to conform as closely as possible to the International Unit.), (tablets) "60 mg. (1 Gr.)" and (capsules) "1½ gr. (0.1 Gm.)" were false and misleading as applied to the articles which contained substantially less than their declared potency, namely, (powdered digitalis) 10 International Units per gram, (tablets) 1 grain per tablet, and (capsules) 1½ grains per capsule.

DISPOSITION: 10-14-58. Default—destruction.

5753. Digitalis tablets. (F.D.C. No. 42170. S. No. 35-125 P.)

QUANTITY: 3 2,000-tablet btl. at Woodbury, N.J.

SHIPPED: 7-22-58, from Philadelphia, Pa., by Raymer Pharmacal Co.

LABEL IN PART: (Btl.) "2000 Tablets Allen's English Digitalis 1½ Grains
* * * Standardized to U.S.P. Requirements for Powdered Digitalis."

RESULTS OF INVESTIGATION: Examination showed that the digitalis potency of the article was significantly less than its professed potency of 1½ grains of United States Pharmacopeia digitalis per tablet.

LIBELED: 9-4-58, Dist. N.J.